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July 10, 2003

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OSWER Docket
EPA Docket Center
Environmental Protection Agency
Mailcode: 5305T
1200 Pennsylvania Ave. NW.
Washington DC 20460
Attention Docket ID No. RCRA-2003-0012

RE: Federal Register, June 3, 2003, Vol 68, No. 106; Environmental Protection Agency; Announcement of A Public Stakeholder Meeting on Management of Hazardous Waste In Research and/or Academic Laboratories

Dear Sir or Madam:

Schering-Plough is an international pharmaceutical company that discovers, develops, and manufactures human and animal health care products. We devoted over $1.4 billion of our net sales in 2002 to research and development and employ over 1,000 laboratory researchers in the United States alone. In addition, we employ several hundred personnel in analytical laboratories to insure our drugs are safe and effective for the patients using them. We therefore take interest in the topics presented at the above meeting and offer the following comments on the categories discussed:

1. Hazardous Waste Determination, Labeling, and Training

   The RCRA regulation has its own unique definition of a 'hazardous waste'. Personnel must be trained on RCRA to make waste determinations. We therefore recommend that only RCRA trained support personnel in waste accumulation or storage areas make waste determinations.

   To facilitate the waste determination process, chemicals from the laboratory should be labeled so RCRA trained personnel in accumulation areas can identify the material to a Material Safety Data Sheet or other technical reference in making a waste determination. It is impractical to put all technical information on the label. In addition, laboratory material can be transferred between multiple containers such as a beaker to a can to a solvent drum. These containers should only be subject to RCRA labeling when they reach an accumulation area.

   Laboratory personnel only need training on a procedure or system for handling waste and not on RCRA. RCRA required training should be limited to support personnel in waste accumulation or storage areas.

2. Satellite Accumulation Time

   Schering-Plough believes the Satellite Accumulation Area (SAA) definition does not work in a laboratory and should not even be used for laboratory operations.

   Regulations say waste in an SAA must be 'at or near the point of generation' and 'under the control of the operator'. We found, after several Federal and State inspections, that no two interpretations are the

same. Some interpret 'at or near' based on physical distance, others require a lock and key to prove control, others base SAA determinations on how frequently containers are emptied.

Secondly, waste in an SAA must be labeled 'hazardous waste'. This has caused problems in inspections regarding when laboratory material must be labeled "hazardous waste". This labeling requires training on RCRA definitions. Applying this SAA requirement to a laboratory undermines any attempt at an alternate system as described under item 1.

Thirdly, small material quantities are often transferred from the bench to other containers as it makes its way to a RCRA accumulation area. Questions arose in past inspections regarding whether a transfer container can be considered a 'satellite accumulation container' when it receives waste from the bench or laboratory. This adds further confusion to the SAA definition.

Finally, only 55 gallons of a waste (1 kg acutely toxic) can be kept in an SAA. This requires detailed monitoring of waste activity in a laboratory and therefore undermines any attempt at streamlining waste handling.

In conclusion, USEPA must seriously consider replacing the SAA definition with a management system requirement for waste handling.

3. Treatment Performed in Laboratories

Laboratory personnel should be allowed to treat waste if it limits hazards to outside personnel. Of particular concern are extremely hazardous chemicals such as water reactive or unstable materials. This material can be found in byproducts, rinses, or container heels remaining from an experiment. Treatment will not increase hazards for the chemist or laboratory already working with the material.

Though USEPA allows treatment, we have had at least one inspection where treatment became an issue because of the regulatory interpretation of what is acceptable. USEPA can encourage treatment by replacing complex and confusing treatment regulations and guidance with a management based system. USEPA can furthermore encourage state and local agencies to adopt this approach and eliminate their own additional interpretations.

4. Other Issues

Quality and Analytical Laboratories:

Quality and analytical laboratories should be included in any regulatory streamlining because the waste issues are the same as in a research laboratory. Schering-Plough is willing to discuss this matter in further detail with USEPA.

State and Local Regulations:

USEPA has delegated RCRA compliance to several states and local agencies. Unless these agencies accept USEPA streamlining efforts, any changes made at the national level will have no impact for several of our facilities. Therefore, we cannot overemphasize the need to strongly encourage swift adoption of any regulation changes at the state and local level.

Management Systems:

Finally, a common thread in this whole process is management systems. Current regulations give too much detail on how to handle waste (i.e. the process). Instead, regulations should define goals and allow regulated entities to develop the appropriate management process. This basic approach would eliminate the complexity and confusion in applying waste regulations to the laboratory. From our experience waste generation can even vary between laboratories within the same facility, depending on the function occurring within a laboratory.

Schering-Plough appreciates USEPA's interest in addressing current difficulties managing laboratory waste. If USEPA desires more information, I can be reached at (908) 629-3781 with questions.

Sincerely,

Daniel Caramagno

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Schering Corporation

cc: Russ Cerchiaro
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